Results of the Patient-Related Outcomes of Mechanical lead Extraction Techniques (PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques

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Abstract: AIMS Several large studies have documented the outcome of transvenous lead extraction (TLE), focusing on laser and mechanical methods. To date there has been no large series addressing the results obtained with rotational lead extraction tools. This retrospective multicentre study was designed to investigate the outcomes of mechanical and rotational techniques. METHODS AND RESULTS Data were collected on a total of 2205 patients (age 66.0 ± 15.7 years) with 3849 leads targeted for extraction in six European lead extraction centres. The commonest indication was infection (46%). The targeted leads included 2879 pacemaker leads (74.8%), 949 implantable cardioverter-defibrillator leads (24.6%), and 21 leads for which details were unknown; 46.6% of leads were passive fixation leads. The median lead dwell time was 74 months [interquartile range (IQR) 41-112]. Clinical success was obtained in 97.0% of procedures, and complete extraction was achieved for 96.5% of leads. Major complications occurred in 22/2205 procedures (1%), with a peri-operative or procedure-related mortality rate of 4/2205 (0.18%). Minor complications occurred in 3.1% of procedures. A total of 1552 leads (in 992 patients) with a median dwell time of 106 months (IQR 66-145) were extracted using the Evolution rotational TLE tool. In this subgroup, complete success was obtained for 95.2% of leads with a procedural mortality rate of 0.4%. CONCLUSION Patient outcomes in the PROMET study compare favourably with other large TLE trials, underlining the capability of rotational TLE tools and techniques to match laser methods in efficacy and surpass them in safety.

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Results of the Patient-Related Outcomes of Mechanical lead Extraction Techniques (PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques

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Aims Several large studies have documented the outcome of transvenous lead extraction (TLE), focusing on laser and mechanical methods. To date there has been no large series addressing the results obtained with rotational lead extraction tools. This retrospective multicentre study was designed to investigate the outcomes of mechanical and rotational techniques.

Methods and results Data were collected on a total of 2205 patients (age 66.0 ± 15.7 years) with 3849 leads targeted for extraction in six European lead extraction centres. The commonest indication was infection (46%). The targeted leads included 2879 pacemaker leads (74.8%), 949 implantable cardioverter-defibrillator leads (24.6%), and 21 leads for which details were unknown; 46.6% of leads were passive fixation leads. The median lead dwell time was 74 months [interquartile range (IQR) 41–112]. Clinical success was obtained in 97.0% of procedures, and complete extraction was achieved for 96.5% of leads. Major complications occurred in 22/2205 procedures (1%), with a peri-operative or procedure-related mortality rate of 4/2205 (0.18%). Minor complications occurred in 3.1% of procedures. A total of 1552 leads (in 992 patients) with a median dwell time of 106 months (IQR 66–145) were extracted using the Evolution rotational TLE tool. In this subgroup, complete success was obtained for 95.2% of leads with a procedural mortality rate of 0.4%.

Conclusion Patient outcomes in the PROMET study compare favourably with other large TLE trials, underlining the capability of rotational TLE tools and techniques to match laser methods in efficacy and surpass them in safety.

Keywords Rotational lead extraction • Evolution extraction sheath • Laser lead extraction • Complication • Technical success

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What's new?

- Largest series of data published on clinical outcomes of a rotational lead extraction tool.
- The Evolution rotational extraction sheath shows a good safety and efficacy performance, especially in long implanted leads.
- The risk for superior vena cava injury when using the Evolution rotational extraction tool is very low.

Introduction

Transvenous lead extraction (TLE) plays an essential role in the long-term management of patients with cardiac implanted electronic devices. Fibrosis and calcification along implanted leads becomes increasingly likely with longer dwell times and simple traction is often not enough to achieve complete removal. Mechanical sheaths were the first widely used tool but were only moderately effective.[1] Powered sheaths, utilizing either laser or radiofrequency energy to break down areas of fibrosis, were the next development. Of the two, laser powered sheaths gained the most traction and several large studies have shown them to achieve very high clinical success rates.[2,3] Concerns have been raised about the risk of major complications when using laser sheaths.[1,2,4]

Rotational dissecting sheaths, characterized by a handle trigger-driven rotational dissecting tip at the end of a flexible sheath, have been available for this application for just over a decade.[5] Rotational tools have been associated with greater efficacy than other non-laser methods in extracting all components of the targeted leads.[6] Safety data from small case series have been promising,[6] but data from larger series, such as that available for laser methods,[3,7] have been lacking. The range of rotational tools has continued to expand, as has the range of accessories for use in association with them to enhance safety and efficacy.[6,8–11]

To date, there is a lack of large volume data on advanced mechanical lead extraction techniques and tools. The PROMET (Patient-Related Outcomes of Mechanical lead Extraction Techniques) study was designed to address this by collecting data from consecutive patients treated in high-volume extraction centres in which rotational tools were the preferred method for TLE in cases not amenable to simple traction.

Methods

Patient population

Patient data were collected from six European lead extraction centres that had maintained a comprehensive record of lead extraction procedures. Five of the six centres fulfilled the criteria of a high-volume extraction centre (>30 procedures/year). Depending on the availability of sufficient data sets in different study centres and based on the retrospective design of this study, the starting point of data collection differed between the centres from as early as January 2005. The local review board at all investigational sites approved the research protocol. The results obtained were analysed retrospectively with regard to efficacy and safety.

Definitions

Success and failure were defined according to the definitions of the 2017 Heart Rhythm Society and the 2018 European Heart Rhythm Association expert consensus.[12] In brief, complete success for the extraction of an individual lead was defined as the removal of all components of that lead from the vascular space without the occurrence of a fatal or permanently disabling complication. A procedure was considered a clinical success if it attained the intended clinical outcome and did not involve the retention of any lead portion >4 cm in length.

Complications were adjudicated by a committee including representatives from each contributing centre. A complication was considered to have occurred if an undesired consequence of the extraction procedure suffering or disability, prolongation of the hospital admission, or a need for additional intervention or pharmacological therapy. Based on definitions *in prior* expert consensus papers,[12–14] a complication was classed as serious if it led to the death of the patient or to persistent disability or if it required a substantial intervention such as cardiac surgery, pericardiocentesis, or vascular surgery. Fatalities were judged to be related to the extraction procedure if they occurred on the day of the procedure or as a consequence of a complication of the procedure.

Statistics

Categorical variables are presented as numbers and percentages. Continuous variables are presented as mean ± standard deviation or as median and interquartile range (IQR), as appropriate. Differences between groups were analysed by two-sample *t*-test. A *P*-value of <0.05 was considered significant.

Results

Patient and lead characteristics

Data were obtained for 2205 patients (69% male, age 66.0 ± 15.7 years; *Table 1*) with 3849 targeted leads for TLE. The mean dwell time of the targeted leads averaged 84.8 ± 61.9 months, with a median of 74 months (IQR 41–112). Seventy-five percent of the targeted leads were pacemaker leads, 25% implantable cardioverter-defibrillator leads.

The most common indication for TLE was infection, present in 46%, but declined non-significantly over the course of the study, representing the primary indication in 47.0% in the first half of each centre's experience compared to 44.0% in the second half.

Techniques and equipment

In all study centres a superior, subclavian approach was chosen as the primary option for lead extraction procedures. Most procedures (68.4%) were performed by cardiac surgeons, working in all cases in either a hybrid theatre (95.6%) or a standard operating theatre (4.4%). The remainder were performed by cardiologists/electrophysiologists, generally working in an electrophysiology laboratory (99.2%). All procedures not performed by a cardiac surgeon were performed with cardiac surgical stand-by including the availability of extracorporeal circulation and a perfusionist.

For leads that could not be extracted by simple traction, a multistep lead extraction approach (individual to each study centre) was performed. A locking stylet (Liberator, Cook Medical, USA) was generally used as the first of these additional steps, making it the most commonly used item of specialized extraction equipment (*Figure 1*).

Table 1 Patient and lead characteristics

Patient characteristics	
Patient number	2205
Age	66.0 ± 15.7 years
Gender	
Male	69%
Female	30%
Unknown	1%
Left ventricular ejection fraction	38.3 ± 16.1%
NYHA class (*n* = 187)	
Class 1	18.7%
Class 2	25.1%
Class 3	40.6%
Class 4	15.5%
Diabetes mellitus (*n* = 419)	22.7%
Chronic renal disease (*n* = 393)	57.3%
Cardiomyopathy (*n* = 542)	
DCM	40.8%
ICM	59.2%
Previous cardiac surgery (*n* = 601)	27.8%
Number of targeted leads	3849
	74.8% pacemaker leads
	24.6% ICD leads
	0.6% information not available
Implant duration	
Mean implant duration	84.7 ± 61.8 months
Median implant duration	74 months (IQR 41–112)
Localisation of leads	
Right atrium	1167 (30.3%)
Right ventricle	2238 (58.1%)
Coronary sinus tributary	395 (10.3%)
SVC	8 (0.2%)
Fragment or unknown	41 (1.1%)
Fixation mechanism	
Active fixation	1560 (40.6%)
Passive fixation	1795 (46.6%)
Information not available	494 (12.8%)

DCM, dilated cardiomyopathy; ICD, implantable cardioverter-defibrillator; ICM, ischaemic cardiomyopathy; IQR, interquartile range; NYHA, New York Heart Association; SVC, superior vena cava.

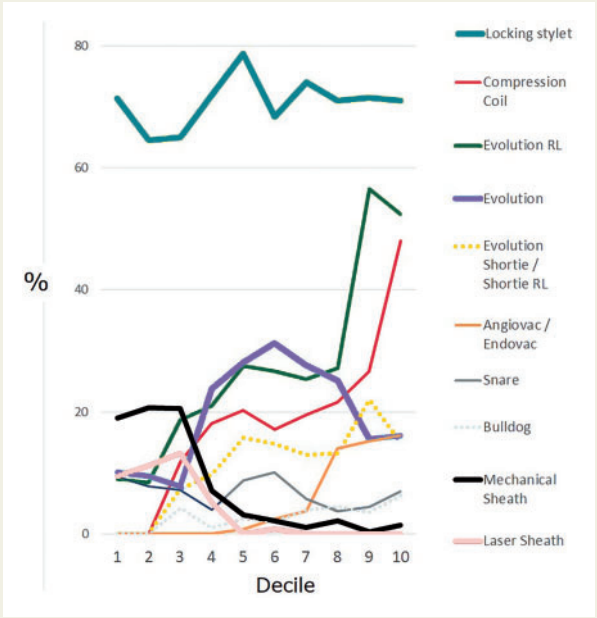

Figure 1 Temporal trends in the equipment used in the PROMET cohort. Laser equipment was almost abandoned by all centres within the first half of the experience. There was increasing uptake of rotational dissection sheaths instead of traction-only or laser methods, with a high and constant background usage of locking stylets.

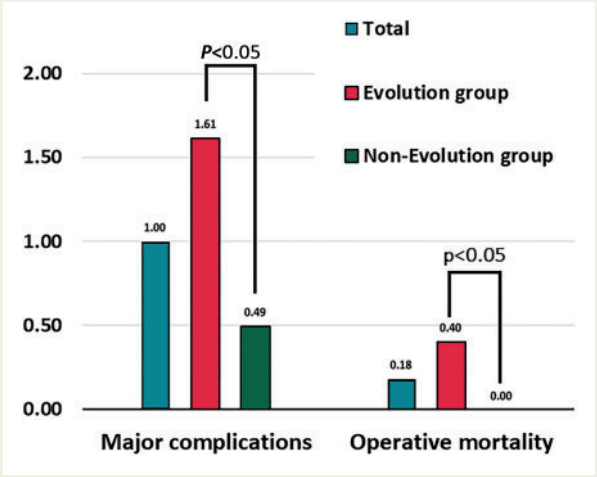

Figure 2 Safety endpoints of the PROMET study in the overall cohort and in the subset in whom rotational dissection sheaths were used.

For 940 leads with a median dwell time of 71 months (IQR 48–93), the locking stylet alone allowed enough additional traction to remove the lead. In other cases, this traction permitted the use of the lead as a rail to guide an extraction sheath.

Dissection sheaths included simple polypropylene models (Byrd Dilator Sheath, Cook Medical, USA), PTFE sheaths (Cook Medical, USA), laser sheaths (SLS II, Philips, USA), and rotational tools (Evolution and Evolution RL, Cook Medical, USA; Tightrail, Philips, USA). Laser sheaths were used for 139 leads (3.6%) with a median dwell time of 57 months (IQR 38–81). Their use was confined to the first half of the case series and they were used in only three centres, accounting for 21% of leads extracted in one centre, fewer than 1% in the other two.

Where a subclavian approach failed or was expected to be impossible, a femoral or an internal jugular approach was performed. In these cases, a variety of snares were used, predominantly the Needle's Eye (Cook Medical, USA) which accounted for 70% of all snare usage.

Table 2 Subgroup analysis of cases with the use of the Evolution rotational sheath vs. cases without Evolution

	Evolution-group (992 patients/1552 leads)	Non-Evolution group (1213 patients/2297 leads)	*P*-value
Median implant duration	106 months (IQR 66–145)	58 months (IQR 28–90)	<0.001
Complete procedural success (per lead)	95.2%	97.3%	0.003
Major complications	1.6%	0.5%	<0.01
Procedure-related mortality	0.4%	0%	<0.05

IQR, interquartile range.

Safety

Major complications occurred in 22 cases (1.0%; *Table 3*, *Figure 2*), and minor complications in 3.1%. Procedure-related mortality occurred in four patients (0.18%), three of whom had systemic infection as the indication for extraction.

Efficacy and efficiency

Among the entire study group (2205 patients/3849 leads), complete technical success was obtained in the extraction of 96.5% of leads, with a clinical success rate of 97.0% of procedures.

Rotational dissection tools

Subgroup analysis was performed for the use of the Evolution or the Evolution RL rotational TLE devices, which were used for 1552 leads in 992 patients. Other devices of the Evolution group including the Evolution Shortie, the Evolution Shortie RL, and the Evolution outer sheath were not included unless used in association with the full-length Evolution or Evolution RL. The Tightrail rotational extraction sheath was not included as the design of this tool is substantially different, and the device was used for only 12 leads.

Leads removed using the Evolution rotational tools had a longer dwell time than others (*Table 2*, *Figure 3*). Despite the implant duration of the leads extracted in the Evolution group, complete procedural success was only 2.1% lower than in the non-Evolution group (95.2% vs. 97.3%).

The major complications encountered in the Evolution group predominantly consisted of right ventricular injuries (*Table 3*). One case of injury to the right atrium and adjacent intrapericardial superior vena cava (SVC) occurred, and one late haemothorax requiring percutaneous drainage (*Table 3*) but no acute injuries to the extrapericardial part of the SVC were encountered.

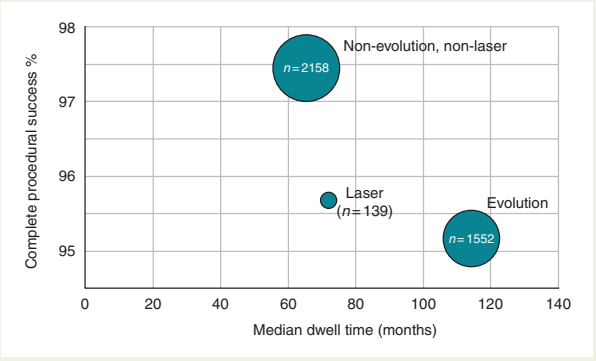

Figure 3 Complete procedural success in per lead extracted, according to the method used to extract the lead.

Discussion

The PROMET study is the largest study to report on efficacy and safety outcomes in patients undergoing mechanical TLE and is comparable in size to the largest series of laser extraction (*Table 4*). The key findings are:

(1) Mechanical tools can deliver a level of efficacy that is equivalent to that of laser powered sheaths.
(2) The use of mechanical tools is associated with a low procedural risk for major and minor complications. The nature of major complications differs from that reported in any of the large series describing laser-based TLE methods, particularly the lower incidence of procedural injuries to the SVC.

Safety

The list of adverse events encountered in the PROMET cohort is remarkable for the low incidence of acute injuries to the SVC, which, in contrast, account for most of the fatal complications of laser TLE.

The low incidence of injury to the SVC demonstrated in the PROMET study constitutes a major advance in TLE. Even in the expert hands represented by the LEXICON and ELECTRa investigators, vascular tears/avulsion occurred in 6/1449 and 20/3510 cases, respectively. In real-world practice, this complication has clinical relevance, demonstrated by two published series of SVC events in the context of the use of compliant endovascular occlusion balloon: the initial series reported 35 surgically confirmed cases of laser-related SVC disruption in the USA during a 6-month period and the follow-up series reported 116 SVC events in a 25-month period.[15,16] Even the lower of these estimates implies an average of more than 4 SVC events per month.

The reported safety results of the PROMET study are in line with the just recently published data of Diaz *et al.*,[4] who compared the observed mortality between laser and rotational extraction sheaths based on the Manufacturer and User Facility Device Experience database. At different market share estimates and with adjustment for potential underreporting in cases with rotational sheaths the relative

Table 3 Major complications

Patient details	Device and lead number	Indication	Dwell time of oldest lead (months)	Equipment used	Complication and treatment	Outcomes
80 years, male	Dual chamber pacemaker	Infection	124	Locking stylet, simple sheath	Cardiac avulsion	Full recovery after surgical repair
83 years, female	Single chamber pacemaker	Infection	151	Locking stylet, simple sheath	Pericardial effusion, percutaneous drainage	Full recovery
37 years, female	Dual chamber pacemaker with abandoned leads (4 leads total)	Infection, local	228	Locking stylets, femoral snare (needle eye)	Pericardial effusion post-procedure, percutaneous drainage	Full recovery
77 years, male	Dual chamber pacemaker	Redundant lead	178	Locking stylet, Evolution (13F), femoral snare (needle eye)	Cardiac avulsion during use of femoral snare	Surgical repair, but died within 30 days
65 years, female	CRT-D	Lead failure	141	Locking stylet, simple sheath, Evolution	Right ventricular injury	Full recovery after surgical repair
46 years, male	Dual chamber pacemaker	Systemic infection	47	Locking stylet	Pericardial tamponade	Full recovery after surgical repair
83 years, female	Dual chamber pacemaker with abandoned leads (total 4 leads)	Infection	>120	Evolution, femoral snare	Pericardial effusion	Uncomplicated recovery after percutaneous drainage
88 years, female	Dual chamber pacemaker (2 leads)	Perforated lead, lying in pleural space	2	Locking stylet	Oesophageal injury from transoesophageal echo probe	Recovered after long hospital stay
80 years, female	Dual chamber pacemaker (2 leads)	Infection	285	Locking stylet, compression coil, Evolution RL (11F)	Peri-procedural stroke	Recovered
43 years, male	Dual chamber ICD with abandoned leads (3 leads)	Infection	66	Evolution	Pericardial tamponade	Full recovery after surgical repair
47 years, female	Single chamber ICD	Lead malfunction	59	Evolution RL	Right pleural collection of blood drained percutaneously at 1 day after extracting right sided device	Full recovery. No surgery, no transfusion required
78 years, female	Dual chamber PPM	Local infection	Unknown	Locking stylet, compression coil, Evolution RL (11F)	Injury to right ventricle	Full recovery after surgical repair
75 years, female	CRT-P (including Starfix lead)	Lead malfunction	15	Locking stylet, compression coil, Evolution RL (9F)	Injury to coronary sinus	Full recovery after surgical repair

Continued

Table 3 *Continued*

Patient details	Device and lead number	Indication	Dwell time of oldest lead (months)	Equipment used	Complication and treatment	Outcomes
63 years, male	CRT-D	Lead malfunction	83	Locking stylet, compression coil, Bulldog, Evolution RL (13F)	Injury to inferior vena cava causing pericardial tamponade	Full recovery after surgical repair
74 years, male	Dual chamber PPM, abandoned leads (total 4 leads)	Venous occlusion, redundant leads, need for upgrade	356	Locking stylets, Evolution 9F	Pericardial tamponade due to RV perforation	Full recovery after surgical repair
78 years, female	Dual chamber pacemaker	Local infection	Unknown	Liberator, compression coil, Evolution 9F	Tamponade due to RV perforation	Full recovery after surgical repair
79 years, male	CRT-D with redundant leads (total 7 leads)	Septicaemia	79	Liberator, compression coil, Evolution RL 13F	Septic shock	Peri-procedural death
37 years, male	Dual chamber ICD	Lead malfunction	83	Simple stylet	Pericardial tamponade	Full recovery after surgical repair
83 years, female	CRT-D	Local infection	126	Liberator, compression coil, Evolution RL 13F	Pericardial tamponade	Initial recovery after surgical repair, but died at 30 days
65 years, male	CRT-D	Systemic infection	105	Liberator, compression coil, Evolution RL 13F	Left-sided haemothorax	Full recovery after surgical placement of a chest drain
61 years, female	Single chamber pacemaker with redundant leads (3 leads in total)	Septicaemia	208	Liberator, compression coil, Evolution RL 13F	Injury to junction of SVC and RA leading to pericardial tamponade	Died at 2 days post-procedure despite surgical repair
48 years, male	Single chamber ICD	Systemic infection	4	Liberator, compression coil, Evolution RL 13F	Damage to tricuspid valve requiring subsequent valve surgery	Full recovery after surgical repair

CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; ICD, implantable cardioverter-defibrillator; PPM, permanent pacemaker; RA, right atrium; RV, right ventricle.

Table 4 Comparison of the results of the PROMET study with other published large volume studies

	Patients/leads	Indications	Leads	Implant duration (months)	Success rates	Major complications	In-hospital mortality
PROMET study	2205/3849	46.0% infection	74.8% pacemaker leads	Mean 84.7 ± 61.8	96.5% CPS	1%	1.7% (30-day mortality)
		54.0% non-infectious	24.6% ICD leads	Median 74.0	97.0%		
			0.6% unknown	IQR (41.0–112.0)	CS		
LEXICON study	1449/2405	56.9%	70.0% pacemaker leads	Median 82.1	96.5% CPS	1.4%	1.86%
		Infection	29.2% ICD leads	IQR (0.4–356.8)	97.7%		
		43.1%	0.7% unknown		CS		
		Non-infectious					
ELECTRa study	3510/4917	52.8% infection	75.7% pacemaker leads	Mean 76.8 ± 64.8	95.7% CPS	1.7%	1.4%
		47.3% non-infectious	24.3% ICD leads	Median 60.0	96.7%		
				IQR (24.0–108.0)	CS		

CPS, complete procedural success; CS, clinical success; ICD, implantable cardioverter-defibrillator; IQR, interquartile range.

risk for mortality was significantly higher in laser sheath extractions than in procedures with the use of a rotational extraction sheath.

Efficacy

The clinical success rate and complete procedural success rates for leads targeted for removal in the PROMET series compare favourably with other large patient cohorts in TLE procedures such as the Lexicon study[3] and the ELECTRa registry.[17] The efficacy of the Evolution rotational TLE device was proven by the achievement of complete procedural success in more than 95% of leads with median implant durations of 106 months, substantially longer than in previous large TLE studies.[3,17]

Limitations

The major limitation of this study is its retrospective study design. The acquired data represents real-world data in a number of centres in different nations over a period of just over a decade. Due to the retrospective design and the individual data recording in the different participating centres, data recording may not have been complete in all cases. Despite this fact, the authors believe that this data is of relevant clinical importance for the lead extraction community and supports the hypothesis of a satisfactory safety profile and high efficacy of rotational extraction sheaths, as seen in previous smaller series.[6,8,10,11,18]

Conclusions

This large series of cases show that an extraction service based on rotational dissecting tools can deliver a procedural mortality rate of <0.2%, and that a service based on these products can deliver complete lead extraction in over 96% of leads targeted. In this series, rotational TLE tools showed a low incidence of major complications, especially of SVC injuries. The efficacy of rotational TLE tools was proven by the achievement of high success rates in leads with long implant durations.

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